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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

UPRETI, ASHUTOSH

ART UNIT PAPER NUMBER

2623

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/992,242		AIAZIAN, ARAM	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ashutosh Upreti		2623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/29/2002</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the quality of the current drawings is not sufficient for publication. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Ultrasonic Image Analysis System Utilizing an Echo-Contrast Agent.

### ***Claim Objections***

Claims 7 and 22-25 are objected to because of the following informalities:

Claim 7 cannot depend from claim 9 as claims can only depend from preceding claims.

As to claims 22-25, these claims all claim a method but depend from claim 18, which claims a system (changing the word "method" to "system" on line 1 of all the mentioned claims will cure this problem).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 9, the use of “may be”, “selectively defined” and “with or without” is confusing and indefinite.

Claims not specifically addressed depend from an indefinite claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10, 14, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan (U.S. Patent 5,734,739) in view of Clark (U.S. Patent 6,174,285) and Klotz (U.S. Patent 5,852,646).

As to claim 1, Sheehan discloses displaying electronic image signals (Figure 1, 40). Also disclosed is use of an imaging device that sends electronic signals of an image (Figure 1, 16). Also disclosed is an A-D converter (Figure 1, 30), an image data storage device (Figure 1, 32) and a computer processor (Figure 1, 34). The device inherently has computer-executable software that can receive electronic signals and

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can convert electronic signals into electronic data, as it is necessary for the device to work. Also inherent (and represented by the lines between the boxes in Figure 1) is electronic communication means, as without such means, the disclosed device cannot work. The line between 28 and 30 in Figure 1 indicates that the imaging device is electronically coupled to other portions of the device that transmit the electronic signals. Sheehan further discloses injecting contrast material into the body region (column 8, lines 13-14). In this case Sheehan refers to radio-contrast material as the reference is dealing with x-rays, but the Sheehan mentions that it is also applicable to ultrasound (column 8, lines 26-27). One of ordinary skill in the art would know to substitute a radio-contrast material for echo-contrast material if using ultrasound instead of x-rays. Sheehan further discloses scanning a body region in one pre-defined time period (Column 9, line 37). Here the cardiac cycle is considered to be one pre-defined time period. Also disclosed is displaying a multidimensional view of a body region (column 8, lines 1-3). Multidimensional is read as an image having more than one dimension and since contours are displayed, Sheehan clearly deals with two- dimensional images.

Sheehan does not expressly disclose automatically dividing images representing a multidimensional view into user-defined segments.

Clark discloses a scan controller controlled in accordance with the user's preset view (column 3, lines 59-60). This derives (considered automatic, as the need for user initiation is not disclosed) a view of a selected anatomical feature from a 3D data set (column 3, lines 63-64). This is considered dividing into user-defined segments as the

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user has defined one segment to be the anatomical feature and the remaining data is considered to be another segment.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the segmentation of Clark with the imaging of Sheehan as they both deal with processing and displaying medical images of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would improve the effectiveness with which relevant information is presented to the user.

Sheehan also does not expressly disclose eliminating baseline data from an image.

Klotz discloses eliminating baseline data from an image (column 5, lines 1-4).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the image subtraction of Klotz with the image processing of Sheehan as they both deal with medical image processing.

One of ordinary skill in the art would have been motivated to do this, as it would improve the effectiveness with which relevant information is presented to the user.

As to claims 2 and 3, Sheehan as applied above further discloses calculating individual pixel intensity (column 9, lines 36-37). This is also read as calculating the overall intensity of a segment as the left ventricle (LV) discussed here is considered to be a segment and every pixels levels (i.e. overall) are being processed. The change of pixel intensity is calculated over time as gray scale values of the same location are calculated over successive images during the time period (column 9, lines 51-53).

As to claim 4, Sheehan as applied above further discloses displaying a plurality of selected multidimensional views obtained at distinct predetermined time periods (column 7, lines 41-43).

As to claim 5, Klotz as applied above further discloses calculating and displaying data reflecting changes in images between distinct predetermined time periods (column 5, lines 1-4). Here, each image reflects the difference between the times when the M and C images were taken. One is taken when there is no contrast material in the heart and the other when there is contrast material (column 4, lines 62-64). The time difference between these two states is considered to be the pre-determined time period in this case.

As to claim 6, Sheehan discloses using the images for diagnosis (column 8, lines 59-60) i.e. before treatment. Also disclosed is using the images during a procedure (column 9, lines 7-8). If the physician looks at the images toward the end of the medical procedure, then some medical treatment has already taken place, so they are, in a way, being viewed after some medical treatment. Sheehan, however, does not expressly disclose viewing an image after medical treatment. The examiner takes official notice that it is well known in the art to view medical images before and after medical treatment. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to view the images before and after treatment as medical images are often viewed at such times.

One of ordinary skill in the art would have been motivated to do this, as viewing medical images before treatment can aid in diagnosis and viewing medical images after treatment can enable one to check how effective the treatment was.

As to claim 10, Sheehan as applied above further discloses data calculated by a user-defined technique involving calculating mean electronic signal intensity (column 11, lines 31-33).

As to claim 14, Sheehan does not expressly disclose that the imaging device is an ultrasonic transducer. Clark as applied above further discloses that the imaging device is an ultrasonic transducer (column 2, line 67).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the ultrasonic transducer of Clark with the imaging of Sheehan as they both deal with processing and displaying medical images of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would enable a user to receive more information about a selected body portion. In addition to this, Sheehan teaches that its methods are applicable to ultrasound (column 8, lines 26-27).

As to claim 17, Sheehan as applied above further discloses that the body region is a portion of the myocardium (heart muscle) (column 7, line 46).

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Clark and Klotz as applied to claim 1 above, and further in view of Grenon (U.S. Patent 6,258,033).



As to claim 7, the combination of Sheehan and Clark and Klotz does not expressly disclose measuring perfusion through the body region. Grenon discloses measuring the perfusion in the body region by calculating the amount of contrast agent (column 5, lines 54-55).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the perfusion measurement of Grenon with the combination of Sheehan and Clark and Klotz, as they both deal with medical image processing of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would improve the relevant information available for a physician for medical decision-making.

As to claim 8, the combination of Sheehan and Clark and Klotz does not expressly disclose automatically determining size and location of a perfusion defect area and automatically comparing it to a respective corresponding area. Grenon discloses automatically determining size and location of a perfusion defect area (column 5, lines 46-48) and automatically comparing data from respective perfusion defect areas (column 5, lines 54-55). Here a defect area is compared to a Normalized Region of Interest (NROI), which is calculated from previous data of the same body region.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the perfusion defect area calculations of Grenon with the combination of Sheehan and Clark and Klotz, as they both deal with medical image processing of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would improve the relevant information available for a physician for medical decision-making.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Clark and Klotz as applied to claim 10 above, and further in view of Kamiyama (U.S. Patent 5,993,391).

As to claim 11, the combination of Sheehan and Clark and Klotz does not expressly disclose displaying a time intensity curve of the electronic data. Kamiyama discloses displaying a time-intensity curve of the electronic data (column 10, lines 10-12).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the time intensity curves of Kamiyama with the combination of Sheehan and Clark and Klotz, as they both deal with medical image processing.

One of ordinary skill in the art would have been motivated to do this, as it would improve the relevant information available for a physician for medical decision-making.

As to claim 12, the limitations are rejected for the same reasons as in claim 11. Kamiyama discloses the display of one time-intensity curve as it deals with only one body region (column 10, lines 49-50). When dealing with more than one body segment, one of ordinary skill in the art would realize that you would display more than one time-intensity curve (i.e. one for each body segment).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Clark and Klotz as applied to claim 1 above, and further in view of Reisfeld (U.S. Patent 6,301,496).

As to claim 13, the combination of Sheehan and Clark and Klotz does not expressly disclose color-coding user-defined segments. Reisfeld discloses color-coding (using pseudocolor) user-defined segments of a human heart (Figure 10 and column 27, lines 13-15).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the color-coding of Reisfeld with the combination of Sheehan and Clark and Klotz, as they both deal with medical image processing of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would make it easier for a user to identify different portions of a body part.

Claims 15, 16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Clark and Klotz as applied to claim 1 above, and further in view of Yock (U.S. Patent 6,221,015).

As to claim 15, Yock discloses an imaging device (display is mentioned in column 3, line 32) coupled to a catheter device (column 3, line 1).

As to claim 16, Yock, discloses positioning an imaging device adjacent to a desired body region, within a respective body vasculature (column 3, line 8).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the catheter and imaging device of Yock with the

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combination of Sheehan and Clark and Klotz, as they both deal with medical image processing of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would allow a physician to get close-up images from within the heart, aiding diagnosis and treatment.

As to claim 18, the limitations of the claim are rejected for the same reasons as in claims 1, 3 and 14-16.

Regarding the system using ultrasound; having an imaging device coupled to a catheter device; and the imaging device being intravascular, these limitations are discussed in claims 14-16 respectively.

Regarding the system sending and displaying electronic image signals and eliminating background data, these limitations are discussed in claim 1.

Regarding calculating time-based intensity change, this limitation is discussed in claim 3.

As to claim 19, the limitations of the claim are rejected for the same reasons as in claim 14.

As to claim 20, Clark as applied above further discloses that the multi-dimensional displays are three-dimensional (column 3, lines 44-46).

As to claim 21, the limitations of the claim are rejected for the same reasons as in claim 1.

As to claim 22, the limitations of the claim are rejected for the same reasons as in claim 2.

As to claim 23, the limitations of the claim are rejected for the same reasons as in claim 3.

As to claim 24, the limitations of the claim are rejected for the same reasons as in claim 4.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Clark and Klotz and Yock as applied to claim 18 above, and further in view of Grenon.

As to claim 25, the combination of Sheehan and Clark and Klotz and Yock does not expressly disclose automatically determining size and location of a perfusion defect area and automatically comparing it to a respective corresponding area. Grenon discloses automatically determining size and location of a perfusion defect area (column 5, lines 46-48) and automatically comparing data from respective perfusion defect areas (column 5, lines 54-55). Here a defect area is compared to a Normalized Region of Interest (NROI), which is calculated from previous data of the same body region.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the perfusion defect area calculations of Grenon with the combination of Sheehan and Clark and Klotz and Yock, as they both deal with medical image processing of the heart.

One of ordinary skill in the art would have been motivated to do this, as it would improve the relevant information available for a physician for medical decision-making.


**Contact Details**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ashutosh Upreti whose telephone number is (703) 306 4087. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.U.  
February 1, 2005

  
Jon Chang  
Primary Examiner